

failing to enforce HIPAA requirements, CMS assesses whether the affected individual or entity has made reasonable efforts to exhaust available State remedies. As part of its assessment, CMS may contact State officials regarding the questions raised.

§ 150.211 Notice to the State.

If CMS is satisfied that there is a reasonable question whether there has been a failure to substantially enforce HIPAA requirements, CMS sends, in writing, the notice described in § 150.213 of this part, to the following State officials:

- (a) The governor or chief executive officer of the State.
- (b) The insurance commissioner or chief insurance regulatory official.
- (c) If the alleged failure involves HMOs, the official responsible for regulating HMOs if different from the official listed in paragraph (b) of this section.

§ 150.213 Form and content of notice.

The notice provided to the State is in writing and does the following:

- (a) Identifies the HIPAA requirement or requirements that have allegedly not been substantially enforced.
- (b) Describes the factual basis for the allegation of a failure or failures to enforce HIPAA requirements.
- (c) Explains that the consequence of a State's failure to substantially enforce HIPAA requirements is that CMS enforces them.
- (d) Advises the State that it has 30 days from the date of the notice to respond, unless the time for response is extended as described in § 150.215 of this subpart. The State's response should include any information that the State wishes CMS to consider in making the preliminary determination described in § 150.217.

§ 150.215 Extension for good cause.

CMS may extend, for good cause, the time the State has for responding to the notice described in § 150.213 of this subpart. Examples of good cause include an agreement between CMS and the State that there should be a public hearing on the State's enforcement, or evidence that the State is undertaking expedited enforcement activities.

§ 150.217 Preliminary determination.

If, at the end of the 30-day period (and any extension), the State has not established to CMS's satisfaction that it is substantially enforcing the HIPAA requirements described in the notice, CMS takes the following actions:

- (a) Consults with the appropriate State officials identified in § 150.211 (or their designees).
- (b) Notifies the State of CMS's preliminary determination that the State has failed to substantially enforce the requirements and that the failure is continuing.
- (c) Permits the State a reasonable opportunity to show evidence of substantial enforcement.

§ 150.219 Final determination.

If, after providing notice and a reasonable opportunity for the State to show that it has corrected any failure to substantially enforce, CMS finds that the failure to substantially enforce has not been corrected, it will send the State a written notice of its final determination. The notice includes the following:

- (a) Identification of the HIPAA requirements that CMS is enforcing.
- (b) The effective date of CMS's enforcement.

§ 150.221 Transition to State enforcement.

(a) If CMS determines that a State for which it has assumed enforcement authority has enacted and implemented legislation to enforce HIPAA requirements and also determines that it is appropriate to return enforcement authority to the State, CMS will enter into discussions with State officials to ensure that a transition is effected with respect to the following:

- (1) Consumer complaints and inquiries.
- (2) Instructions to issuers.
- (3) Any other pertinent aspect of operations.

(b) CMS may also negotiate a process to ensure that, to the extent practicable, and as permitted by law, its records documenting issuer compliance and other relevant areas of CMS's enforcement operations are made available for incorporation into the records of the State regulatory authority that